

**IN THE UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION**

UNITED STATES OF AMERICA,)	
)	
Plaintiff,)	
)	
v.)	Civil No.
)	
THOMAS H. GARRETT, M.D.,)	
)	
Defendant.)	

COMPLAINT

Plaintiff, the United States of America (“United States”), on behalf of the United States Drug Enforcement Administration (“DEA”), alleges:

Introduction

1. This civil action seeks civil monetary penalties under the Controlled Substances Act, 21 U.S.C. § 801, et seq., against Defendant Thomas H. Garrett, M.D (“Garrett”).

Jurisdiction and Venue

2. This Court has jurisdiction pursuant to 21 U.S.C. § 842(c)(1) and 28 U.S.C. §§ 1345 and 1355. Venue is proper in the Western District of Missouri pursuant to 28 U.S.C. § 1395.

Parties

3. Plaintiff is the United States, suing on behalf of the DEA, an agency of the United States Department of Justice, with its district office located in Overland Park, Kansas. The DEA is the federal entity charged with enforcement of the substantive laws described in this Complaint.

4. Defendant Thomas H. Garrett, M.D. is a licensed medical doctor, DEA Registration Number AG2007967. During the course of the events described in this Complaint, Garrett moved

his office from Lake Convenience Clinic, High Point Shopping Center, Highway 54, Osage Beach, Missouri to Lake Convenience Clinic, 100 College Boulevard, Lake Ozark, Missouri.

Applicable Federal Statutes

5. The Controlled Substance Act (“CSA”) divides drugs into five (5) schedules, depending on whether the particular drug has a currently accepted medical use. Restriction on the manufacture and distribution of the drug depends on which schedule the drug has been assigned. United States v. Oakland Cannabis Buyers’ Club, 532 U.S. 483, 491-492 (2001).

6. Drug abuse and drug trafficking in the United States is tracked, in part, through the record keeping provisions of the CSA. Legislative history of the Act reveals congressional concern to reduce the diversion of drugs from the legitimate course of commerce into illegal channels (citation omitted). Congress intended strict compliance with the record keeping provisions, with strict liability to attach for civil violations. United States v. Green, 905 F.2d 694, 697-98 (3rd Cir.), cert. denied, 498 U.S. 985 (1990).

7. The CSA, 21 U.S.C. § 842(a)(5), provides that it shall be unlawful for any person “to refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required” for controlled substances. Violators shall be subject to a civil monetary penalty of not more than \$10,000 per violation under 21 U.S.C. § 842(c)(1)(B).

Factual Background

8. On May 25, 1995, investigators from the Bureau of Narcotics and Dangerous Drugs (“BNDD”), an agency of the State of Missouri, located in Jefferson City, Missouri, conducted an inspection and audit of Garrett's office at the Lake Convenience Clinic, Osage Beach, Missouri.

9. Garrett's record keeping practices violated several provisions of the United States Code and Regulations, including the following:

(a) No biennial inventory was taken for controlled substances. 21 C.F.R. §1304.11(c); in violation of 21 U.S.C. § 842(a)(5).

(b) Complete and accurate receipt records were not retained for Schedule II - V Controlled Substances because the records were missing Garrett's DEA Registration Number. 21 C.F.R. §§ 1304.04(a),1304.21(a); in violation of 21 U.S.C. § 842(a)(5).

(c) No required dispensing records were maintained for December 1994, and January 1995, and Garrett failed to maintain dispensing records for Lorcet and Halcion samples¹, Schedule III and IV Controlled Substances, respectively. 21 C.F.R. §§ 1304.03(b),1304.21(a), in violation of 21 U.S.C. § 842(a)(5).

10. On December 5, 1995, investigators from the DEA conducted an inspection of Garrett's office at the Lake Convenience Clinic, Osage Beach, Missouri. Again, investigators examined Garrett's controlled substance records.

11. Patty Garrett, office manager and wife of Thomas Garrett, admitted to investigators that before the May 25, 1995 BNDD inspection, no inventory had ever been taken. The first complete inventory was taken on May 26, 1995.

12. During the December 5, 1995 DEA inspection, the investigators reviewed twenty-four (24) patient files. Thirty-two (32) prescriptions were compared with information contained in the patient files. Two (2) prescriptions were not noted in the respective patient's record.

¹ Lorcet (Vicodin) is a Schedule III controlled substance used for pain treatment. Halcion (Triazolam) is a Schedule IV controlled substance used for short-term treatment of insomnia.

13. The DEA Investigators informed Mrs. Garrett, as office manager, of the record keeping requirements mandated by federal law, including the following:

(a) The complete product description of the controlled substances, including package size, must appear on the inventory;

(b) The “controlled substance on hand” should be the total number of full and partial containers of each product, not the total number of tablets;

(c) The dispensing log must show a patient's full address;

(d) The “amount received” column should only have an entry on the day that controlled substances are received from the supplier; the new amount may be added to the “balance on hand” column;

(e) The “amount dispensed” should be one for each commercial container of product dispensed to each patient; and

(f) Controlled substance receipt records must contain the date of receipt, and the amount of product actually received. The initials of the person receiving the product should be noted on the packing slip used as the receipt record. 21 C.F.R. § 1304.22(a)(2)(iv), 21 U.S.C. § 842(a)(5).

14. On January 8, 1996, following an informal conference at the Missouri BNDD, a five-year Settlement Agreement was entered between Garrett and the BNDD (“BNDD Agreement”). The BNDD Agreement called for stringent adherence to controlled substance regulations by Garrett, as well as maintenance of a perpetual inventory and exact copies of issued prescriptions. Garrett was issued a probated/restrictive BNDD controlled substance registration effective January 8, 1996. A copy of the BNDD Agreement is attached as Exhibit A.

15. On or about August 1998, Garrett entered into an agreement with the DEA “DEA Agreement” with the same terms set forth by the BNDD Agreement. See Exhibit B attached.

16. On March 25, 2004, investigators from the BNDD conducted another inspection of Garrett's office at the Lake Convenience Clinic, Osage Beach, Missouri, specifically looking at his controlled substance records. A copy of the BNDD Authorization and Consent to Inspect Records and Inspection Report is attached as Exhibit C.

17. During the inspection the following record keeping and code violations were observed:

(a) Garrett failed to maintain an annual inventory. Mo. Code Regs. Ann. 19 § 30-1.042(1).

(b) Garrett failed to dispose of outdated controlled substances. Mo. Code Regs. Ann. 19 § 30-1.078(1).

(c) Garrett failed to witness wastage of controlled substances. Mo. Code Regs. Ann. 19 § 30-1.078(4)(E).

(d) Garrett failed to maintain complete and accurate records. Mo. Code Regs. Ann. 19 § 30-1.044(1), in violation of 21 C.F.R. § 1304.21(a) and 21 U.S.C. § 842(a)(5).

(e) Garrett failed to provide required information on dispensing labels. V.A.M.S. §195.100.5, and

(f) Garrett failed to maintain records of receipt with required information. Mo. Code Regs. Ann. 19 §§ 30-1.048(4) and 21 C.F.R. § 1304.22(i)(iii), in violation of 21 U.S.C. § 842(a)(5).

18. On April 9, 2004, a BNDD investigator informed Garrett of the discrepancies found during the March 25, 2004 inspection of Garrett's office. Garrett agreed to attempt to reconcile the audit within fifteen (15) days and provide documents to verify Garrett's suggested changes.

19. Also in the spring of 2004, a patient of Dr. Garrett's ("Patient A") contacted DEA to complain about Garrett's scheduled drug dispensing practices. Patient A alleged Garrett was charging him/her \$45.00 per narcotic prescription and billing it as an office visit. Patient A further alleged Garrett required him/her to provide random urinalysis samples. In some cases, the random urinalyses were requested more than twice per week, at a cost of \$180.00 for each sample.

20. DEA investigators interviewed Patient A on April 9, 2004, regarding his/her complaint against Garrett. Garrett operated on a cash-for-prescription basis. Garrett charged Patient A \$45.00 for each of the following narcotic prescriptions:

- A. OxyContin²;
- B. Percocet³;
- C. Soma⁴;
- D. Neurontin⁵;
- E. Klonopin⁶;

² OxyContin (oxycodone hydrochloride), a Schedule II Controlled Substance, is a controlled release narcotic painkiller.

³ Percocet (acetaminophen oxycodone hydrochloride), a Schedule II Controlled Substance, is a narcotic analgesic which reduces pain and fever.

⁴ Soma (Carisoprodol) relieves acute, painful muscle strains and spasms.

⁵ Neurontin (Gabapentin) is an anticonvulsant and can be also prescribed for pain syndromes.

⁶ Klonopin (Clonazepam), a Scheduled IV Controlled Substance, is used for convulsive or panic disorders.

- F. Lorazepam⁷, and
- G. Mirtazapine⁸.

Patient A usually saw a nurse or receptionist instead of Garrett. He/she would pay them cash for the prescription, and occasionally have his/her blood pressure checked. Patient A would leave without seeing Dr. Garrett. Garrett billed this as an “office visit”.

21. Garrett required Patient A to sign an agreement restricting Patient A from selling drugs he/she obtained from Garrett and required Patient A to submit to drug tests in Garrett’s office. Garrett charged a fee of \$60.00-\$185.00 each day for the drug test.

22. On or about April 21, 2004, Garrett notified BNDD by letter that as of May 1, 2004, he would no longer stock controlled substances for dispensing or administering. A copy of this letter is attached as Exhibit D.

23. On or about April 23, 2004, Garrett admitted in a letter to BNDD that he was unable to reconcile the March 25, 2004 audit and inspection by BNDD. See Exhibit E.

24. On August 19, 2004, DEA investigators conducted another inspection of Garrett's office at the Lake Convenience Clinic, Osage Beach, Missouri. A copy of the DEA Notice of Inspection is attached as Exhibit F.

25. The investigators asked Garrett for all his controlled substance records including receipt records, distribution, and/or dispensing logs for the two years leading up to August 19, 2004.

⁷ Lorazepam (Ativan), a Scheduled IV Controlled Substance, is used for the treatment of anxiety disorders.

⁸ Mirtazapine (Remeron), is an antidepressant.

The receipt records⁹ and dispensing logs provided by Garrett in response to this request are attached as Exhibits G and H.

26. Garrett informed the investigators he no longer stored or dispensed controlled substances from Lake Convenience Clinic and he had no controlled substances onsite. Garrett signed a Closing Inventory of Controlled Substances record dated August 19, 2004. A copy of that record is attached as Exhibit I.

27. During the August 19, 2004 inspection, investigators found additional record keeping inadequacies.

28. The following Code violations were observed during this inspection:

(a) Garrett failed to denote the finished form (product description, bottle size and strength) of a controlled substance on a required biennial inventory. 21 U.S.C. § 842(a)(5).

(b) Garrett failed to maintain complete and accurate receipt records for controlled substances, because each of the thirty-three (33) receipt records Garrett provided contain violations of the CSA. 21 U.S.C. § 842(a)(5).

(c) Garrett failed to maintain fifty-seven (57) receipt records for controlled substances from DEA Registrants. 21 U.S.C. § 842(a)(5), and

(d) Garrett failed to maintain complete and accurate controlled substance dispensing records to account for the controlled substances. 21 U.S.C. § 842(a)(5). Exhibit J is a controlled substance accountability chart prepared by DEA agents. This chart shows the controlled substances sold to Garrett from August 19, 2002 to August 19, 2004, but not

⁹Because Garrett received controlled substances from different suppliers, the actual receipt records in Exhibit G may look different; however, each document contains the same information.

physically present at the pharmacy or otherwise accounted for (by sale or destruction) in Garrett's office records.

29. On September 14, 2004, DEA investigators conducted an inspection of Osage Village Pharmacy, Osage Beach, Missouri. A copy of the DEA Notice of Inspection is attached as Exhibit K. The investigators asked for all records of wholesale sales to Garrett and his clinic.

30. The investigators requested copies of Osage Village Pharmacy's wholesale distribution records from August 1, 2002 to September 14, 2004. Pharmacist Wilcox provided the investigators a summary printout, and two invoices as the official record for all distributions from Osage Village Pharmacy to Lake Convenience Clinic from August 1, 2002 to September 14, 2004, which included dates after Garrett said he was done dispensing controlled substances. Ms. Wilcox also provided a copy of the last biennial inventory for her pharmacy dated April 21, 2004. See attached Exhibits L, M and N.

31. In addition, Ms. Wilcox provided investigators a copy of prescription history for not only Garrett himself, but the following office employees or family members of Garrett: Tracie Henningsen (a part-time employee of Garrett's), Jeanette Renfro (Garrett's office receptionist), Jennifer Fry (Garrett's office assistant), Patty Garrett, and Patient A. See Exhibit O.

32. On November 24, 2004, investigators returned to Lake Convenience Clinic, Lake Ozark, Missouri, to interview Garrett. During the interview, Garrett stated he had not stocked or dispensed any controlled substances as of May 1, 2004.

33. Despite assurances by Garrett to the contrary, on November 23 and 24, 2004, investigators found seven (7) packaging inserts for Ambien, a Schedule IV Controlled Substance, in the trash dumpster of the clinic parking lot. Investigators obtained two controlled substance

request records from a known supplier, SANOFI-SYNTHELABO, INC., DEA #RS02000939, with Garrett's signature, documenting the request and receipt of packages of Ambien, a schedule IV controlled substance, on or about August 31, 2004 and October 7, 2004. Garrett did not have an explanation for the packaging found in his trash dumpster and could not provide documentation to account for the distribution of all the received product.

34. As a result of Garrett's actions, Garrett is liable to the United States for civil monetary penalties in the amount of \$930,000.00.

COUNT ONE

Violation of the Controlled Substances Act, 21 U.S.C. § 842(a)(5)

35. This Count is a claim for civil monetary penalties under the Controlled Substances Act, 21 U.S.C. § 801, *et seq.*

36. The allegations set forth in paragraphs 1 through 35 are incorporated in this Count.

37. On August 19, 2004, an on-site investigation by DEA of Garrett's office at the Lake Convenience Clinic, Osage Beach, Missouri, revealed Garrett's record keeping violated the following provisions:

(a) failure to denote the finished form of a controlled substance on a required biennial inventory;

(b) failure to maintain complete and accurate receipt records for controlled substances, in that each of the thirty-three (33) receipt records that Garrett provided contain violations of the CSA;

(c) failure to maintain fifty-seven (57) receipt records for controlled substances from DEA Registrants; and

(d) failure to maintain complete and accurate controlled substance dispensing records to account for the controlled substances.

38. As a result of the foregoing violation, Garrett is liable to the United States in the amount of \$10,000.00 per violation, for a total amount of \$900,000.00.

COUNT TWO

Violation of the Controlled Substances Act, 21 U.S.C. § 842(a)(5)

39. This Count is a claim for civil monetary penalties under the Controlled Substances Act, 21 U.S.C. § 801, *et seq.*

40. The allegations set forth in paragraphs 1 through 38 are incorporated in this Count.

41. On November 23 and 24, 2004, DEA investigators went to interview Garrett at the Lake Convenience Clinic, Lake Ozark, Missouri. During this visit, investigators found the following items at the clinic: seven (7) packaging inserts for Ambien, a Schedule IV controlled substance, in the trash dumpster of the clinic parking lot. Subsequently, DEA investigators obtained two (2) controlled substance request records from a known supplier, SANOFI-SYNTHELABO, INC., DEA #RS02000939, with Garrett's signature, documenting the receipt of Ambien after May 1, 2004. A copy of the Ambien request records are attached as Exhibit P.

42. As a result of the foregoing violation, Garrett is liable to the United States in the amount of \$10,000.00 per violation, for a total amount of \$90,000.00.

COUNT THREE

Violation of the Controlled Substances Act, 21 U.S.C. § 842(a)(5)

43. This Count is a claim for civil monetary penalties under the Controlled Substances Act, 21 U.S.C. § 801, *et seq.*

44. The allegations set forth in paragraphs 1 through 42 are incorporated in this Count.

45. On March 25, 2004, an on-site investigation by BNDD of Garrett's office at the Lake Convenience Clinic, Osage Beach, Missouri, revealed the following controlled substance record keeping violations committed by Garrett in violation of 21 C.F.R. § 1304.21(a) and 21 U.S.C. § 842(a)(5): Garrett failed to maintain complete and accurate records.

As a result of the foregoing violation, Garrett is liable to the United States in the amount of \$10,000.00 per violation, for a total amount of \$10,000.00.

Conclusion

WHEREFORE, the United States prays for judgment against Thomas H. Garrett, M.D., as follows:

1. Under Count One, a civil monetary penalty of not less than \$900,000.00;
2. Under Count Two, a civil monetary penalty of not less than \$90,000.00;
3. Under Count Three, a civil monetary penalty of not less than \$10,000.00.

WHEREFORE, the United States prays this Court enter judgment against defendant Garrett on Counts I, II and III, in the total amount of \$1,000,000.00, and for such other relief deemed just and proper under the circumstances.

Respectfully submitted,

Todd P. Graves
United States Attorney

By: */s/ Jane Pansing Brown*
Jane Pansing Brown, Mo. Bar #30658
Assistant United States Attorney
Charles Evans Whittaker Courthouse
400 E. 9th Street, Suite 5510
Kansas City, Missouri 64106
Telephone: (816) 426-3130
FAX: (816) 426-3165
ATTORNEYS FOR THE PLAINTIFF